

P-4286 (42476)



C. Lawrence
#19
4.10.02

PATENT

~~DO NOT ENTER~~

~~OK TO ENTER~~ IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

~~OK AS ENTERED~~
On re Application of:

Pierre Bierre et al.

Serial No.: 09/223,347 ✓

Filed: December 30, 1998 ✓

For: SYSTEM AND METHOD FOR UNIVERSAL
IDENTIFICATION OF BIOLOGICAL SAMPLES :

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:
: Group Art Unit: 1743 ✓

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: Examiner: LaToya I. Cross ✓

RESPONSE TO FINAL OFFICE ACTION

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the final Office Action mailed on December 18, 2001, the period for response to which has been extended by one (1) month. Reconsideration of this application is respectfully requested in view of the remarks which follow.

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The Examiner is referred to the Applicants' remarks in the Amendment filed on October 5, 2001, at pages 6-8, for a summary of the present invention and its advantages over the prior art. As set forth in independent claim 33, the biological sample identification method of the present invention focuses initially on identifying the container in which a sample is or will be placed, rather than on identifying the sample itself as in the prior art. The container is marked, typically but not necessarily during its initial manufacture, with a *universally unique* identifier. The term "unique"

indicates that no two containers will have the same identifying marking, while the term "universal" indicates that the uniqueness of the container identifier is preserved across institutional or organizational boundaries. When the container is ready to be used, the universally unique identifier is associated (either manually, in a computer database or otherwise) with information relating to a sample that is or will be placed in the container. From that point on, the sample can be tracked using the container identifier alone, without any chance of misidentification, even when the sample travels between different institutions or organizations. Independent claim 43 defines the present invention in somewhat different terms, but includes the requirement of a universally unique identifier as in claim 33.

In the final Office Action, the Examiner has rejected claims 33-50 as being unpatentable over U.S. Patent No. 4,842,153 (Hulon) in view of U.S. Patent No. 5,609,778 (Pulaski et al.). Although the Examiner appears to concede that neither the Hulon '153 patent nor the Pulaski et al. '778 patent teaches the use of a universally unique container identifier that can be used across institutional or organizational boundaries, the Examiner believes that the mention of "bar codes" in the Pulaski et al. '778 patent would suggest to one of ordinary skill in the art that a Universal Product Code (UPC) could be applied to the shipping tube 10 disclosed in the Hulon '153 patent in lieu of the disclosed identification information 32. For the reasons discussed below, the combination proposed by the Examiner does not lead to the present invention as defined in claims 33-50.

As the Examiner is undoubtedly aware, bar codes are not synonymous with UPCs. Some bar codes have meaning only within a given institution or organization. Therefore, it cannot be

assumed that the mere mention of "bar codes" in the Pulaski et al. '778 patent would necessarily lead one of ordinary skill in the art to employ a *universal* code, such as a UPC, on the shipping tubes 10 disclosed in the Hulon '153 patent. However, even assuming that such a modification is suggested by the prior art, the resulting container would be essentially useless for the purposes of the present invention.

As will be apparent from the attached website excerpts, the UPC system most widely used in the United States today, known as UPC Version A, is a 12-digit code. The first digit is known as a number system character, and indicates whether the UPC relates to an ordinary retail product, a pharmaceutical product, a coupon, or the like. The next five digits identify the manufacturer of the product, and the five digits after that make up a product code or item number assigned by the manufacturer. The twelfth and final digit is a check digit, or checksum, that is used to verify that the preceding digits have been scanned correctly.

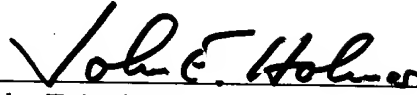
The key point for the purpose of the present discussion is that the five-digit product code or item number portion of a UPC *is the same for all like items sold by a particular manufacturer*. Taking the example given in one of the attached website excerpts, the item number 01134 found on a three-liter bottle of Diet Coke will be the same for *all* three-liter bottles of Diet Coke. Similarly, if the product in question were a test tube or vial, rather than a soft drink, the item number portion of the UPC would be identical for *all* like test tubes or vials produced by the same manufacturer. This is an essential requirement of a UPC, since it allows a retailer to charge the same price for a given type of product each time that the product is scanned and sold to a customer.

It can therefore be seen that UPCs, although universal, are not *unique* identifiers of the type contemplated by the present invention. To be useful in the Applicants' method, the identifier must be different for each *individual* container, not merely for each *type* of container manufactured by a given manufacturer. It is only then that the container identifier can be associated in a one-to-one manner with information relating to a biological sample placed in the container, and used thereafter to identify the sample, as set forth in Applicants' claim 33.

The combination proposed by the Examiner also fails to acknowledge another aspect of the present invention as defined in independent method claims 33 and 43, that is, the step of associating the universally unique container identifier with certain other information. The other information may be "information relating to [a] a biological sample" placed in the container as recited in claim 33, or "information pertaining to use, planned use or contents of [the] container" as recited in claim 43. Even if the identification information 32 imprinted on the shipping tube 10 of the Hulon '153 patent were replaced with a UPC, there is no suggestion in either of the two references relied upon by the Examiner that an end user would seek to associate the UPC with a biological sample placed in the tube, or with a use, planned use or contents of the tube. Given that the UPC would not uniquely identify the container, such associations would be of little value in any event.

In view of the foregoing arguments, withdrawal of the outstanding rejections and allowance of claims 33-50 is respectfully requested. Should the Examiner wish to discuss any aspect of this application with the Applicants' representative, the Examiner is invited to contact the undersigned attorney at the local telephone listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John E. Holmes", written over a horizontal line.

John E. Holmes
Reg. No. 29,392
Attorney of Record

Roylance, Abrams, Berdo & Goodman, L.L.P.
1300 19th Street, N.W., Suite 600
Washington, DC 20036
(202) 659-9076

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